CLAIMS

1. Microparticulate oral galenical form for the delayed and controlled release of at least one active principle - excluding perindopril - this active principle having an absorption window in vivo that is essentially limited to the upper parts of the gastrointestinal tract,

said form being designed so as to guarantee its therapeutic efficacy by guaranteeing its absorption in vivo,

wherein :

⇒ in that the release of the active principle is governed by two different triggering mechanisms, one being based on a variation in pH and the other allowing the release of the AP after a predetermined residence time in the stomach,

⇒ in that its dissolution behavior in vitro (determined as indicated in the European Pharmacopeia, 3rd edition, under the title: "Dissolution test for solid oral forms": type II dissolutest performed under SINK conditions, maintained at 37°C and agitated at 100 rpm) is such that:

- at a constant pH of 1.4, the dissolution profile includes a latency phase with a duration less than or equal to 5 hours,
- and the change from pH 1.4 to pH 6.8, during the latency phase, results in a release phase that starts without a latency period.

2. Galenical form according to claim 1, wherein the dissolution profile includes a latency phase with a duration of between 1 and 5 hours.

3. Galenical form according to claim 1, wherein

it comprises "reservoir" microcapsules containing at least one active principle - excluding perindopril - these microcapsules being of the type that:

- ◆ consist of particles of active principle each coated with at least one film, this coating film consisting of a composite material which:
  - ○ comprises:
    - • at least one hydrophilic polymer A carrying groups that are ionized at neutral pH,
    - • and at least one hydrophobic compound B;
  - ○ and represents a mass fraction (% by weight, based on the total mass of the microcapsules) of ≤40;
- ◆ and have a diameter below 2000 microns,

the coating film of these microcapsules consists of a composite based on A and B in which:

the weight ratio B/A is between 0.45 and 1.0,

and the hydrophobic compound B is selected from products that are crystalline in the solid state and have a melting point T_{fB} such that $T_{fB} \geq 40°C$.

4. Galenical form according to claim 3, wherein the microcapsules have a diameter of between 200 and 800 microns, wherein the weight ratio B/A is between 0.5 and 1.0 and wherein the hydrophobic compound B is selected from products that are crystalline in the solid state and have a melting point T_{fB} such that $40°C \leq T_{fB} \leq 90°C$

5. Galenical form according to claim 3, wherein the hydrophilic polymer A is selected from:

- (meth)acrylic acid/alkyl (e.g. methyl) (meth)acrylate copolymers and mixtures thereof;
- cellulose derivatives, preferably cellulose acetate and/or phthalate, hydroxypropyl methyl cellulose phthalate and hydroxypropyl methyl cellulose acetate and/or succinate;
- and mixtures thereof.

6. Galenical form according to claim 3, wherein the hydrophilic polymer A is selected from:

- (meth)acrylic acid/ methyl(meth)acrylate copolymers and mixtures thereof;
- cellulose acetate and/or phthalate, hydroxypropyl methyl cellulose phthalate and hydroxypropyl methyl cellulose acetate and/or succinate;
- and mixtures thereof.

7. Galenical form according to claim 3, wherein the compound B is selected from the following group of products:

- vegetable waxes, taken on their own or in mixtures with one another;
- hydrogenated vegetable oils, taken on their own or in a mixture with one another;
- monoesters and/or diesters and/or triesters of glycerol with at least one fatty acid, taken by themselves or in a mixture with one another;
- and mixtures thereof.

8. Galenical form according to claim 3, wherein the compound B is selected from the following group of products:

- vegetable waxes, taken on their own or in mixtures with one another;
- hydrogenated vegetable oils, taken on their own or in a mixture with one another;

- mixtures of at least one monoester and of at least one diester and/or of at least one triester of glycerol with at least one fatty acid;
- and mixtures thereof.
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9. Galenical form according to claim 7 or 8 wherein the compound B is selected from the group comprising hydrogenated cottonseed oil, hydrogenated soybean oil, hydrogenated palm oil, glyceryl behenate, hydrogenated castor oil, tristearin, tripalmitin, trimyristin , wax yellow, suppository bases or hard fat, anhydrous milk fat, lanolin, glyceryl palmitostearate, glycerylstearate, lauryl macrogolglycerides, cetyl alcohol, polyglycryl diisostearate, diethylene glycol monostearate, ethylene glycol monostearate, Omega 3 and any mixtures thereof.

10. Galenical form according to claim 7 or 8 wherein the compound B is selected from the group of hydrogenated cottonseed oil, hydrogenated soybean oil, hydrogenated palm oil, glyceryl behenate, hydrogenated castor oil, tristearin, tripalmitin, trimyristin and any mixtures thereof.

11. Galenical form according to claim 3 wherein the compound B is selected from the group comprising
the products which tradenames (trademarks) are the followings : Dynasan, Cutina, Hydrobase, Dub, Castorwax, Croduret, Compritol, Sterotex, Lubritab, Apifil, Akofine, Softtisan, Hydrocote, Livopol, Super Hartolan, MGLA, Corona, Protalan, Akosoft, Akosol, Cremao, Massupol, Novata, Suppocire, Wecobee, Witepsol, Lanolin, Incromega, Estaram, Suppoweiss, Gelucire, Precirol, Emulcire, Plurol diisostearique, Geleol, Hydrine et Monthyle;
as well the additives which codes are the followings : E 901, E 907, E 903 and mixtures thereof;
and mixtures thereof.

12. Galenical form according to claim 3 wherein the compound B is selected from the group comprising the products which tradenames (trademarks) are the followings: Dynasan P60, Dynasan 114, Dynasan 116, Dynasan 118, Cutina HR, Hydrobase 66-68, Dub HPH, Compritol 888, Sterotex NF, Sterotex K, Lubritab and mixtures thereof.

13. Galenical form according to claim 3 wherein the coating film of the microcapsules is free from talc.

14. Galenical form according to claim 1, wherein, at a constant pH of 1.4, the

controlled release phase following the latency phase is such that the release time for 50% of the active principle ($t_{½}$) is defined as follows (in hours):

$$0.25 \leq t_{½} \leq 35$$

15. Galenical form according to claim 1, characterized in that the release phase following the change from pH 1.4 to pH 6.8, which takes place without a latency period, is such that the release time for 50% of the active principle ($t_{½}$) is defined as follows (in hours):

$$0.25 \leq t_{½} \leq 20$$

16. Galenical form according to claim 3, wherein the microcapsules comprise a single composite coating film AB.

17. Galenical form according to claim 3, wherein the active principle is deposited on a neutral core with a diameter of between 200 and 800 microns.

18. Galenical form according to claim 3, wherein the neutral core contains sucrose and/or dextrose and/or lactose.

19. Galenical form according to claim 18, wherein the neutral core is a cellulose microsphere.

20. Galenical form according to claim 1, wherein the active principle used belongs to at least one of the following families of active substances: antiulcer agents, antidiabetics, anticoagulants, antithrombics, hypolipidemics, antiarrhythmics, vasodilators, antiangina agents, antihypertensives, vasoprotectors, fertility promoters, labor inducers and inhibitors, contraceptives, antibiotics, antifungals, antivirals, anticancer agents, anti-inflammatories, analgesics, antiepileptics, antiparkinsonian agents, neuroleptics, hypnotics, anxiolytics, psychostimulants, antimigraine agents, antidepressants, antitussives, antihistamines and antiallergics.

21. Galenical form according to claim 20, wherein the active principle is selected from the following compounds: amoxicillin, metformin, acetylsalicylic acid, pentoxifyllin, prazosin, acyclovir, nifedipine, diltiazem, naproxen, ibuprofen, flurbiprofen, ketoprofen, fenoprofen, indomethacin, diclofenac, fentiazac, estradiol valerate, metoprolol, sulpiride, captopril, cimetidine, zidovudine, nicardipine, terfenadine, atenolol, salbutamol, carbamazepine, ranitidine, enalapril, simvastatin, fluoxetine, alprazolam, famotidine, ganciclovir, famciclovir, spironolactone, 5-asa, quinidine, morphine, pentazocine,

paracetamol, omeprazole, metoclopramide and mixtures thereof.

22. Galenical form according to claim 1, which is a form selected in the group comprising : a tablet, a powder and a gelatin capsule.

23. Use of the microcapsules as defined in claim 1 for the preparation of microparticulate oral galenical forms as tablets.

24. Galenical form according to claim 1 or 23, which is a tablet that disperses in the mouth.